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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,887	02/20/2002	Jerome F. McAleer	SELF.P-016-3	1254
27777	7590	12/20/2004	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			NOGUEROLA, ALEXANDER STEPHAN	
		ART UNIT	PAPER NUMBER	
			1753	

DATE MAILED: 12/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/869,887	MCALEER ET AL.
	Examiner	Art Unit
	ALEX NOGUEROLA	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 September 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-14 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 20 February 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/04/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of September 30, 2004 does not render the application allowable.

Status of Rejections Pending since the Office action of June 06, 2004

2. All previous rejections are withdrawn.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,241,862 B1 in view of

Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 12 provides all of the limitations of claim 1 except for having the pH of the integrated reagent/blood separation layer buffered to a level of around pH 5. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of claim 12 of U.S. Patent No. 6,241,862 B1 because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

5. Claim 2 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 1, from which claim 2 depends, has been addressed above. Claim 13 provides the additional limitation required by claim 2.

6. Claim 3 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 2, from which claim 3 depends, has been addressed above. Claim 14 provides the additional limitation required by claim 3.

7. Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 3, from which claim 4 depends, has been addressed above. Claim 15 provides the additional limitation required by claim 4.

8. Claim 5 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 4, from which claim 5 depends, has been addressed above. Claim 16 provides the additional limitation required by claim 5.

9. Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 5, from which claim 6 depends, has been addressed above. Claim 17 provides the additional limitation required by claim 6.

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10. Claim 7 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 14 and 18 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 3, from which claim 7 depends, has been addressed above. Claim 18 provides the additional limitation required by claim 7.

11. Claim 8 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 14 and 19 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 7, from which claim 8 depends, has been addressed above. Claim 19 provides the additional limitation required by claim 8.

12. Claim 9 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 14 and 20 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 7, from which claim 9 depends, has been addressed above. Claim 20 provides the additional limitation required by claim 9.

13. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the combination of claims 14 and 21 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 9, from which

claim 10 depends, has been addressed above. Claim 21 provides the additional limitation required by claim 10.

14. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) (“Pollmann”). Claim 1, from which claim 11 depends, has been addressed above. As stated in the rejection of claim 1, “it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.”

15. Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) (“Pollmann”). Claim 14 provides all of the limitations of claim 12.

16. Claim 13 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) (“Pollmann”). Claim 12, from which claim 13 depends, has been

addressed above. Claim 14 provides all of the limitations of claim 13 except for disclosing including citrate in the reagent blood separation layer. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of claim 13 of U.S. Patent No. 6,241,862 B1 because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

17. Claim 14 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14 of U.S. Patent No. 6,241,862 B1 in view of Pollmann et al. (US 5,288,636) ("Pollmann"). Claim 1, from which claim 14 depends, has been addressed above. Claim 14 of U.S. Patent No. 6,241,862 B1 provides all of the limitations of claim 14 except for disclosing including citrate in the reagent blood separation layer. Pollmann teaches a disposable test strip comprising at least two conductive elements with a reagent layer

adjacent the conductive elements, the reagent layer including a redox mediator, an enzyme, and a buffer. See the abstract and Figures 1-3. Pollmann further teaches using a citrate buffer (col. 7:59-61), which Applicants implicitly acknowledge buffers to around pH 5 (see claim 11). It would have been obvious to one with ordinary skill in the art at the time the invention was made to use buffer as taught by Pollmann in the invention of claim 14 of U.S. Patent No. 6,241,862 B1 because as taught by Pollmann the buffer will provide a satisfactory pH for enzymatic activity. See col. 4:13-17 and col. 7:55-58. More particularly, it would have been obvious to use citrate buffer because Pollmann teaches that citrate helps stabilize glucose oxidase (see claim 9 of the instant application). Alternatively, the choice of buffer (pH) from known buffers in the art is just a matter of optimizing the enzymatic reaction as it was known at the time of the invention that most enzymes have limited active pH ranges.

18. Claim 14 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). the difference in scope between claims 11 and 14, if any, is not readily apparent.

Final Rejection

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola

Primary Examiner

AU 1753

December 16, 2004